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8 510(k) Summary

8.1 Trade/Proprietary Name

Disetronic Rapid and Rapid D Subcutaneous Infusion Sets

8.2 Common/Usual Name

Subcutaneous Infusion Sets

8.3 Classification Name

Intravascular Administration Sets

8.4 Substantial Equivalence

The Disetronic Rapid and Rapid D Subcutaneous Infusion Set are substantially equivalent to Pharma-Plast Pureline Contact Subcutaneous Infusion set (K945617), Maersk Medical Pureline Comfort (Disetronic Tender) Subcutaneous Infusion Set (K972135) and MiniMed Sof-set QR Infusion Sets (K942181).

8.5 Device Description

The Disetronic Rapid and Disetronic Rapid D Subcutaneous Infusion Sets are administration sets intended to deliver medications under the skin. Both connect at the female Luer to a reservoir, which, for example, can be delivered through the use of an external infusion pump or by manual injection. The stainless steel cannula is inserted into the subcutaneous tissue and fixed into place by an attached approximate circular disk bandage with medical grade adhesive. The tubing of both types of infusion sets is made of polyethylene.

The Disetronic Rapid D Infusion Set has the identical components as the Rapid Set except for two additional components that allow the set to be disconnected approximately 10 cm from the insertion site (variable length anticipated). The disconnect mechanism on the reservoir side has a stainless steel needle. A protector cap is also provided to maintain clean conditions during disconnection and to cover the needle connector. The patient side of the disconnect mechanism has a polyisoprene septum that mates with the needle connector and can be used for manual injections. The Rapid D Subcutaneous Infusion Set includes a separate protector cap to be used to cover the disconnect mechanism while the set is disconnected. The disconnect mechanism may have an additional bandage with medical adhesive grade.

8.6 Intended Use

Disetronic Rapid and Disetronic Rapid D Infusion sets are intended to be used by health care professionals and patients to deliver insulin and other medications under the skin. These sets are intended to be used with manual injection and infusion and automated infusion with infusion pumps.

8.7 Technological Characteristics

The technological characteristics are the same as the predicate devices.

8.8 Performance Data

Product is in compliance with existing international standards and protocols and equivalent to the predicate devices.

8.9 Conclusion

Based on the design equivalency and performance and safety testing, Disetronic Medical Systems has determined that the Disetronic Rapid and Rapid D Subcutaneous Infusion Sets are substantially equivalent to the devices currently marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 5 2001

Disetronic Medical Systems AG
C/O David E. Chadwick
Director of Regulatory Affairs
Disentronic Medical Systems, Incorporated
5151 Program Avenue
Saint Paul, Minnesota 55112-1014

Re: K003977
Trade Name: Disetronic Rapid and Disetronic Rapid D
Subcutaneous Infusion Sets
Regulatory Class: II
Product Code: FPA
Dated: December 21, 2000
Received: December 22, 2000

Dear Mr. Chadwick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003977

Device Name:
Disetronic Rapid and Disetronic Rapid D Subcutaneous Infusion Sets

Indications for Use:
Disetronic Rapid and Disetronic Rapid D Infusion Sets are indicated for the infusion and/or injection of insulin and other medications into the body below the surface of the skin.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
510(k) Number K003977